subpart E of part 807 of this chapter subject to § 886.9.

[52 FR 33355, Sept. 2, 1987, as amended at 65 FR 2321, 2000]

### § 886.5870 Low-vision telescope.

(a) *Identification.* A low-vision telescope is a device that consists of an arrangement of lenses or mirrors intended for use by a patient who has impaired vision to increase the apparent size of objects. This generic type of device includes handheld or spectacle telescopes.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35607, Sept. 14, 1988; 66 FR 38814, July 25, 2001]

### § 886.5900 Electronic vision aid.

(a) *Identification.* An electronic vision aid is an AC-powered or battery-powered device that consists of an electronic sensor/transducer intended for use by a patient who has impaired vision or blindness to translate visual images of objects into tactile or auditory signals.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

[55 FR 48443, Nov. 20, 1990, as amended at 59 FR 63014, Dec. 7, 1994; 66 FR 38814, July 25, 2001]

### § 886.5910 Image intensification vision aid.

(a) *Identification.* An image intensification vision aid is a battery-powered device intended for use by a patient who has limited dark adaptation or impaired vision to amplify ambient light.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35607, Sept. 14, 1988; 66 FR 38814, July 25, 2001]

### § 886.5915 Optical vision aid.

(a) *Identification.* An optical vision aid is a device that consists of a magnifying lens with an accompanying AC-powered or battery-powered light source intended for use by a patient who has impaired vision to increase the apparent size of object detail.

(b) *Classification.* Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[55 FR 48443, Nov. 20, 1990, as amended at 59 FR 63014, Dec. 7, 1994; 66 FR 38815, July 25, 2001]

### § 886.5916 Rigid gas permeable contact lens.

(a) *Identification.* A rigid gas permeable contact lens is a device intended to be worn directly against the cornea of the eye to correct vision conditions. The device is made of various materials, such as cellulose acetate butyrate, polyacrylate-silicone, or silicone elastomers, whose main polymer molecules generally do not absorb or attract water.

(b) *Classification.* (1) Class II if the device is intended for daily wear only.

(2) Class III if the device is intended for extended wear.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is

required before a device described in paragraph (b)(2) of this section may be commercially distributed. See §886.3.

[52 FR 33355, Sept. 2, 1987, as amended at 59 FR 10284, Mar. 4, 1994]

### §886.5918 Rigid gas permeable contact lens care products.

(a) *Identification.* A rigid gas permeable contact lens care product is a device intended for use in the cleaning, conditioning, rinsing, lubricating/rewetting, or storing of a rigid gas permeable contact lens. This includes all solutions and tablets used together with rigid gas permeable contact lenses.

(b) *Classification.* Class II (Special Controls) Guidance Document: ''Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.''

[62 FR 30987, June 6, 1997]

### §886.5925 Soft (hydrophilic) contact lens.

(a) *Identification.* A soft (hydrophilic) contact lens is a device intended to be worn directly against the cornea and adjacent limbal and scleral areas of the eye to correct vision conditions or act as a therapeutic bandage. The device is made of various polymer materials the main polymer molecules of which absorb or attract a certain volume (percentage) of water.

(b) *Classification.* (1) Class II if the device is intended for daily wear only.

(2) Class III if the device is intended for extended wear.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before a device described in paragraph (b)(2) of this section may be commercially distributed. See §886.3.

[52 FR 33355, Sept. 2, 1987, as amended at 59 FR 10284, Mar. 4, 1994]

### §886.5928 Soft (hydrophilic) contact lens care products.

(a) *Identification.* A soft (hydrophilic) contact lens care product is a device intended for use in the cleaning, rinsing, disinfecting, lubricating/rewetting, or storing of a soft (hydrophilic) contact lens. This includes all solutions and tablets used together with soft (hydrophilic) contact lenses and heat disinfecting units intended to disinfect a soft (hydrophilic) contact lens by means of heat.

(b) *Classification.* Class II (Special Controls) Guidance Document: ''Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.''

[62 FR 30988, June 6, 1997]

### §886.5933 [Reserved]

# PART 888—ORTHOPEDIC DEVICES

## Subpart A—General Provisions



## Subpart B—Diagnostic Devices



## Subpart C [Reserved]

## Subpart D—Prosthetic Devices